UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,599	02/02/2001	John Craig Smith	P 276655 LDSG/Z70655/US	6247

7590 10/22/2002

FISH & RICHARDSON P.C.
225 FRANKLIN STREET
BOSTON, MA 02110

EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/22/2002 15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/773,599	Applicant(s) SMITH, JOHN CRAIG	
	Examiner Juliet C Einsmann	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This correspondence supercedes the restriction requirement mailed 5/13/02. Applicant's election with traverse of invention I in paper number 11 is acknowledged, however, after reconsideration, the restriction requirement has been modified. A telephone call was made to Janis Fraser on 9/24/02 to request an election in view of the new requirement, but an election was not made. Thus, the restriction requirement is set forth below in its entirety. Portions of applicants traversal are moot in light of the new requirement, and the remaining portions are addressed following the presentation of the new restriction requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 3, 4, 5, 7, and 8, drawn to a method for the diagnosis of a polymorphism using nucleic acid analysis and the diagnosis of a disease, classified in class 435, subclass 6.

II. Claims 1, 2, 3, 4, 5, and 16, drawn to a method for the diagnosis of a polymorphism using nucleic acid analysis and the treatment of a human, classified in class 435, subclass 6, and class 424, subclass 94.1.

III. Claims 1, 6, 7, 9 and 17, drawn to a method for the diagnosis of a polymorphism using protein analysis, classified in class 435, subclass 7.1 and class 424, subclass 94.1.

IV. Claims 10-15, drawn to isolated nucleic acids, classified in class 536, subclass 23.1.

V. Claims 18 and 19, drawn to a method to prepare a medicament and a pharmaceutical pack, classified in class 424, for example.

VI. Claim 20-22, drawn to a computer readable medium comprising nucleic acids, classified in class 702, subclass 19.

Further Restriction Requirement Applicable to All Groups

Each group detailed above reads on more than one patentably distinct group, wherein each of the distinct group is claims or utilizes one of the distinct polymorphism that are recited within the claims. For example, group I above encompasses eight different inventions, that is, methods for detecting each of the eight different nucleic acid polymorphisms, and group II encompasses two different inventions, that is, methods for detecting each of the two polypeptide polymorphisms recited. For the elected group (of groups I-VI), applicants must further elect single polymorphism for examination in the appropriate product or method claim. Applicant should identify the polymorphism being elected as well as any particular SEQ ID NO's related to the polymorphism, as appropriate. For example, if applicant elects group I, applicant should further elect one of the nucleotide polymorphisms for examination. Each polymorphic sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications.

Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims. Applicant is advised that examination will be restricted to only the elected SNP and SEQ ID NO. and this restriction should not to be construed as a species election.

The inventions are distinct, each from the other because of the following reasons:

3. Each polymorphic sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications. A reference against one would not anticipate or obviate another, and thus for each particular sequence a separate search of the patent and non-patent literature is required. These separate searches would impose undue burden on the examiner.

4. Inventions I, II, III, and V are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods with different goals, distinct method steps and requiring different reagents and different techniques. The methods of inventions I and II require the detection of nucleic acid polymorphisms, and require the use of nucleic acid analysis techniques, such a DNA sequencing or nucleic acid hybridization assays. The methods of invention I are further directed towards the diagnosis of disease, and require a diagnostic step

utilizing nucleic acid techniques, while the methods of invention II have the goal of treating humans and require a step of administering a drug to a human in need of treatment. It is noted that the methods of inventions I and II have some claims in common. In this case, claims 1, 2, 3, 4, and 5 will be examined with either group I or group II, if one of these is elected. The methods of invention III are drawn to the detection of polymorphisms in amino acid sequences, and require the use of protein analysis techniques such as ELISA or polypeptide sequencing, and also include the treatment of a human. The methods of group V are directed towards the preparation of medicaments and would require the steps and reagents necessary to prepare the particular medicament for the treatment of disease.

5. Inventions I and IV, inventions II and VI, inventions I and VI, and inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions IV can each be used in separate methods from those instantly disclosed. The nucleic acids of invention IV can be used in other methods, such as to express the encoded polypeptide, for nucleic acid purification assays and for aptamer assays. The computer readable medium can be used in other methods such as for sequencing methods or capture assays for the detection of target molecules.

6. Invention III is unrelated to the products of group IV, V and VI. The products of invention IV are unrelated to the methods of inventions V and V. The methods of invention II are unrelated to the products of inventions V and VI. Invention V is unrelated to invention VI.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the groupings represents unrelated inventions because the products are not disclosed for use in the particular methods provided. For example, the pharmaceutical pack of group V is not disclosed for use in the methods for diagnosing polymorphisms of group I. Likewise, the nucleic acids of group IV are not disclosed for use in the methods for preparing medicaments of group V. In each case, the products and methods are not necessary for the practice of the unrelated inventions.

7. The products of groups IV, V, and VI are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acids of Group IV are composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The medicament of group V is a chemical compound designed to have bioaffecting activity for the treatment of disease. The computer readable medium is comprised of a silicone chip or a disk or some hard structure with nucleic acids attached or a memory storage device (such as a computer disk) that has sequence information. Furthermore, the products of Groups IV, V, and VI can be used in materially different processes, for example, the DNA of Group IV can be used in hybridization assays, the computer readable medium of group VI can be used in sequencing reactions and methods to determine sequence identity and he pharmaceutical pack can be used to treat disease or conditions associated with the EP1-R gene. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups IV, V, and VI are patentably distinct from each other.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VI require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Response to Traversal

Applicant traverses for a number of reasons.

First, applicant points out that all of the polymorphism relate to a single gene and its encoded protein, and in this regard the polymorphisms are highly related. However, this is not persuasive. From a patentability standpoint, each polymorphism is a separate and distinct invention, each one has its own particular structure and possible effect on the biological activity of the encoded gene. Applicant argues that a single search will reveal the art relevant to all of these polymorphisms, however, this is simply an inaccurate assertion. Each polymorphism would have to be searched and considered separately, and while some pieces of art may be

relevant to more than one polymorphism, this is not necessarily the case given the vast amount of prior art with regard to polymorphisms and the lack of uniformity with regard to the way polymorphisms are reported in the prior art.

Applicant further argues that restriction between a given nucleotide polymorphism and its corresponding amino acid residue polymorphism seems particularly unwarranted. However, the restriction is proper because the methodologies used to detect the polymorphism in a nucleic acid are different from those methodologies used to detect the polymorphism in a polypeptide sequence, and thus, the searches for the two different types of methods are not coextensive.

Applicant points out that certain groups all share a common classification. However, this is not persuasive. Each of the cited classes are quite large, containing hundreds of subclasses and thousands upon thousands of patents within them. Sharing a "class" therefore, does not necessarily mean that a search can be efficiently be conducted for separate and distinct inventions. Further, the search of each of these inventions will also require the search of non-patent literature using different databases and keywords for each type of invention.

Finally, applicant points out that claim 1 covers determining the sequence "at one or more" of the eight nucleotide positions and two amino acid residue positions. However, the claims as written only require a single position be examined, and thus, a restriction to a single position is proper. The requirement does not prohibit applicant from filing claims which require the diagnosis of more than one polymorphism, it merely establishes that methods which require only one are separate and distinct from one another.

For all of these reasons, the restriction requirement is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C Einsmann
Examiner
Art Unit 1634

October 17, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600